

REMARKS

Claims 1, 3-6, 9-15 and 23-32 are presently pending in the instant Application. In the instant Amendment, Claims 1, 3-6, and 9-15 have been canceled, without prejudice. Thus, the Claims that remain pending in the instant Application are Claims 23-32.

Claim Objections

Claims 12-15 have been objected to as being dependent upon a rejected base claim and reciting non-elected subject matter, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and deleting non-elected subject matter.

In the instant Amendment, Claims 12-15 have been canceled, without prejudice. Hence, this objection to Claims 12-15 is MOOT.

Withdrawn Rejections

Claims 1 and 11 had been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner has withdrawn this rejection.

Claims 14 and 15 had been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner has withdrawn this rejection.

Allowed Claims

In the Office Action mailed April 29, 2009, the Examiner admitted that Claims 23-32 are free of the prior art search and made of record, and allowed these Claims. This admission and allowance is appreciated.

The Invention is Nonobvious

Claims 1, 4-6 and 9-11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Devroe *et al.* (BMC Biotechnology August 2002), U.S. Patent 5,624,803 (the ‘803 patent) and Chang *et al.* (Current Gene Therapy, 2001, 1: 237-251). Furthermore,

Claims 1, 4-6 and 9-11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. published patent application publication Number 2004/0234504 (the ‘504 application), the ‘803 patent and Chang *et al.*

The Examiner contends that arguments filed with the USPTO on January 8, 2009 were fully considered but in the Examiner’s opinion, were not persuasive. The Examiner believes it has been argued that the Examiner has not provided any evidence in support of the statement that the claimed U6 promoter and the U6 promoter are patentably indistinguishable. The Examiner also contends it was argued that Chang *et al.* teach the REV element is not necessary and therefore the claimed invention is clearly novel and nonobvious.

It is the Examiner’s position that the claimed U6 promoter and the U6 promoter taught by the ‘508 patent differ by one nucleotide and because, in the Examiner’s opinion, the ‘803 patent teaches the essential elements required for the U6 promoter to initiate transcription of an oligonucleotide insert (see column 13 and Figure 4B) which the claimed U6 promoter sequence has, the Examiner has taken the position the two promoters are patentably indistinguishable. The Examiner has asserted the ‘803 patent teaches U6 promoters mutations that are capable of initiating transcription of an oligonucleotide insert, and that no evidence has been provided that the prior art U6 promoter would not be capable of being used in the claimed retroviral vector nor why it would not have been obvious to use the U6 promoter taught in the ‘803 patent.

In addition, the Examiner has taken the position that previous arguments regarding the teachings of Chang *et al.* are not persuasive. The Examiner has asserted the paragraph of Chang *et al.* previously cited as proof that Chang *et al.* teach the rev element is not necessary is taken out of context. The Examiner believes that if the paragraph is read in its entirety, Chang *et al.* do in fact state the rev element is necessary for efficient transport of cells. The

Examiner has also asserted Chang *et al.* teach that others in the art have tried to overcome this requirement when using lentiviral vectors but the vectors have diminished titers and some of the approaches to element this requirement is said vectors is labor-intensive and efficient. Hence, in the Examiner's opinion, Chang *et al.* do not teach that efficient expression from lentiviral vectors does not require the rev element and outlines the consequences of trying to eliminate this requirement.

In the instant Amendment, Claims 1, 4-6 and 9-11 have been canceled, without prejudice. Hence, these rejections are MOOT.

Fees

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account no. 18-1982 for any underpayment, or to credit any overpayments.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

/William C. Coppola/
William C. Coppola
Registration No. 41,686

SANOFI-AVENTIS U.S. Inc.
1041 ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

DOCKET NUMBER: USAV 2002/0187 US PCT